

FEB 06 2002

**510(k) Summary**

Submitter's name and Address: ClearMedical, Inc.
 1776 – 136th Place NE
 Bellevue, WA 98005
 Ph (425) 401-1414
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FDA Registration Number: 3017110

Contact Person: Richard Radford
 Director of Research and Product Development

Date Summary Prepared: August 8, 2001

Trade or Proprietary Name: ClearMedical/Novamedix AV Impulse (AVI) Foot Covers:

5046 – Right Foot, Regular ImPad
 5048 – Left Foot, Regular ImPad
 5057 – Right Foot, Large ImPad
 5059 – Left Foot, Large ImPad

5065 – Regular Impad Pair (containing 5046, 5048)
 5075– Large Impad Pair (containing 5057, 5059)

Common Name: AVI Foot Cover

Classification Name: Sleeve, Limb, Compressible (per 21 CFR section 870.5800)/ JOW

Equivalent Device

The ClearMedical/Novamedix reprocessed Arterial Venous Impulse (AVI) Foot Covers are substantially equivalent to the Novamedix Arterial Venous Impulse (AVI) Foot Covers distributed by Kendall (Part Number 5065, which is composed of Part Numbers 5046 and 5048, and Part Number 5075, which is composed of Part Numbers 5057 and 5059). This determination has been reached based on an evaluation and analysis of the predicate device's technical and promotional labeling and specific tests. For all established indicators of substantial

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510(k) Summary (Cont'd)

equivalence the ClearMedical devices demonstrated equality in safety and performance.

The ClearMedical/Novamedix reprocessed AVIs are a noninvasive prophylaxis for reducing the incidence of deep vein thrombosis. These AVIs are used by adult patients in hospital or home settings.

The AVIs are latex-free, cushioned throughout, and cover maximum foot surface area to distribute pressure evenly over the foot and minimize trauma to untreated areas. The right foot cover is designated with blue graphics, the left with red graphics.

The AVIs have a rigid sole that contains and directs the impulse (simulates the ground) against the venous plantar plexus (network of veins at the sole of the foot). They also have an anatomically shaped bladder that completely covers the plantar plexus. Both the rigid sole and bladder ensure that the venous plantar plexus is completely flattened and stretched (causing the plantar plexus to collapse and empty, which sends a column of blood to the right atrium of the heart) during impulse pumping.

The AVIs have two Velcro hook straps to allow secure fastening, vent holes and a polyethylene tube.

Intended Use

The ClearMedical/Novamedix AVIs are used with an A-V Impulse System Controller (monitors impulse pressure to patient's feet) to reduce the incidence of deep vein thrombosis, reduce pain and swelling after injury and surgery, and increase arterial blood flow. Adult patients use them in hospital or home environments.

Technological Characteristics of ClearMedical/Novamedix AVIs Compared with the Novamedix AVIs

The predicate device and the ClearMedical/Novamedix AVIs contain bladders that inflate at the base of the foot, directing an impulse to the venous plantar plexus. Attached to the AVI is a connector tubing system that connects to the AVI pump. In form, the predicate device and the ClearMedical reprocessed device are substantially equivalent.

Technological indicators of substantial equivalence were identified and included methods of infection control, fit/attachment, bladder function, and velcro adhesion.

510(k) Summary (Cont'd)

The predicate device is delivered to the customer labeled 'non-sterile' whereas the ClearMedical/Novamedix AVIs are delivered to the customer labeled "High Level-Disinfected." ClearMedical's infection control methods meet or exceed the CDC and APIC Guideline for Handwashing and Hospital Environmental Control, 1985, and APIC Guideline for Selection and Use of Disinfectants standards for this class of device.

Summary of the ClearMedical/Novamedix AVI Performance

Based on an assessment of bench tests and non-clinical performance data, we believe that in all relevant safety and performance indicators the ClearMedical/Novamedix AVIs demonstrates substantial equivalence to the predicate devices, the Novamedix AVIs.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 06 2002

Mr. Richard Radford
Director of Research and Product Development
ClearMedical, Inc.
1776 136th Place NE
Belluvue, WA 98005-2328

Re: K012612

Trade Name: ClearMedical/NovaMedix Arterial Venous Impulse (AVI) Foot Covers
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: January 16, 2002
Received: January 17, 2002

Dear Mr. Radford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

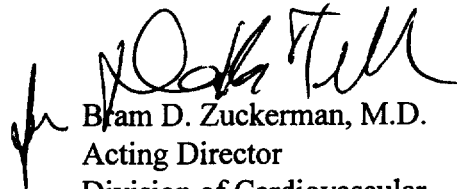
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

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510(K) NUMBER (IF KNOWN): K012612

DEVICE NAME: ClearMedical/Novamedix Reprocessed AVI Foot Cover (without pump)

INDICATIONS FOR USE:

The A-V Impulse System foot pump is safe and effective for the following indications. The proper duration for use of each indication is subject to the clinical judgment of the prescribing physician.

Recommended Guidelines are as follows:

Indication

Recommended Guidelines

Circulation Enhancement For temporary impairments such as temporary trauma or disease conditions, continuous use until the condition is resolved. For chronic impairments, daily use depending on the severity of the patient's condition and activity.

Deep Vein Thrombosis Prophylaxis Continuous use until the patient is fully ambulatory and weight bearing (not just mobilized)

Edema – Acute Continuous use until edema is reduced.


(Please do not write below this line—continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ☐


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Statement of Indications for Use

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510(K) NUMBER (IF KNOWN): K012612

DEVICE NAME: ClearMedical/Novamedix Reprocessed AVI Foot Cover (without pump)

INDICATIONS FOR USE:

Indication

Recommended Guidelines

Edema -- Chronic

As required, but at least 4 hours per day.

*Extremity Pain Incident to
Trauma or Surgery*

Continuous use until severity of pain is reduced or physician recommends alternative therapy.

Leg Ulcers

Continuous use until ulcer severity is reduced or physician recommends alternative therapy.

*Venous Stasis/
Venous Insufficiency*

For temporary impairments such as temporary trauma or disease conditions, continuous use until condition is resolved. For chronic impairments, daily use depending on the severity of the patient's condition and activity level.

(Please do not write below this line—continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ☐

[Signature]
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